

**National Health and Nutrition Examination Survey**

**OMB No. 0920-0237**

(Expires November 30, 2009)

**Change to Conduct Periodontal Feasibility Study**

**Contact Information**

Vicki L. Burt, ScM RN

Chief, Planning Branch

National Health and Nutrition Examination Survey/National Center for Health  
Statistics/CDC

3311 Toledo Road, Room 4211

Hyattsville, MD 20782

Telephone: 301-458-4127

FAX: 301-458-4028

E-mail: [vburt@cdc.gov](mailto:vburt@cdc.gov)

**February 27, 2007**

Supporting Statement (Change)  
National Health and Nutrition Examination Survey (0920-0237)

This is a request for a change to the approval of the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0237, exp. November 30, 2009), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention, to conduct a Periodontal Feasibility Study. This will be a methodological study of oral health questions and examination methods as a component of the NHANES. The NCHS received approval from OMB for field activities for the Main Study of the NHANES 2007-2008 on November 28, 2006.

The NHANES Conditions of Approval stated the following: “With respect to conducting any pilot or nonresponse studies, OMB should be provided with a formal request that describes the specific study design, need for the information, and response burden. OMB will respond within three weeks indicating approval, disapproval, or passback exchanges seeking further information. No pilot or nonresponse studies should be conducted without receipt of approval from OMB.”

The study will be conducted in a Division of Health and Nutrition Examination Surveys’ trailer from April 10, 2007 through June 30, 2007. All details of the study design and need for information are in the attached IRB protocol.

A. Justification

1. Circumstances Making the Collection of Information Necessary.

In section B, page 57 of the approved supporting statement we said the following about this methodological study under the subheading ‘Pilot Testing for 2009-2010’.

“All pilot/feasibility testing must be concurrent to the ongoing data collection within the framework of the survey. DHANES proposes continuing to pilot test the procedures for 2009-2010 as we have done in 2006 for 2007-2008. We plan to start the piloting and developing methods in the spring of 2007. Currently planned are two methodological studies. One involves validation of oral health questions and an examination related to periodontal disease. The second is a validation study of self reported pubertal maturation questions. NHANES will continue to request permission to conduct pilot and methodological studies through the use of the 10-day letter mechanism.”

This change package addresses the underlined study only.

2. Purpose and Use of Information Collection. There are two goals of this proposed study. The first goal is to assess the validity of the questionnaire items by determining the extent to which the items provide an accurate basis for estimating prevalence of clinically-measured periodontitis. The second goal is to assess the operational attributes of a new clinical periodontal assessment module and the

feasibility for use in larger population based studies. Both of these goals will contribute to a long term objective of estimating prevalence of periodontal disease in the U.S. population by using self-report measures. See attached protocol for more details.

9. Explanation of Any Payment or Gift to Respondents. The participants will be paid \$50 after the completion of interview and oral health examination.
  
12. Estimates of Annualized Burden Hours and Cost.

NHANES' respondents will not be involved in this test. The respondent burden is estimated to be 60 minutes per person. The target number of respondents is 436. Therefore, the total burden is 436 hours. The NHANES approved burden included an item for 'followup, special studies, and tests of procedures' for 23,600 hours for 4,000 subjects. This new burden falls within the approved burden for the survey.

There is no cost to individual respondents other than their time to come to the location and to complete the forms.

15. Explanation for Program Changes and Adjustments. There are no changes in this package from the previous-approved clearance.
  
16. Plans for Tabulation and Publication and Project Time Schedule: The study will be conducted in a Division of Health and Nutrition Examination Surveys' trailer from April 10, 2007 through June 30, 2007. The findings will be used to improve the quality of the data. The specific aims that drive the primary analysis are detailed in section 7.1 of the attachment.

#### B. Collections of Information Employing Statistical Methods.

1. Respondent Universe and Sampling Methods. NHANES' respondents will not be involved in this test. Statistical methods will not be used to select participants. Participants will be recruited via advertising and screening for selected characteristics as described in the attached protocol.
  
2. Procedures for the Collection of Information. Details of the data collection, including questions and the oral examination, are found in sections 3 and 4 of the attachment (the IRB protocol).

List of Attachments:

IRB/Ethics Review Board protocol